101-535

Public Law 101-535
101st Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to prescribe nutrition labeling for foods, and for other purposes.

Nov. 8, 1990
[H.R. 3562]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Nutrition Labeling and Education Act of 1990.
21 USC 301 note.

SECTION 1. SHORT TITLE, REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the "Nutrition Labeling and Education Act of 1990".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. NUTRITION LABELING.

(a) NUTRITION INFORMATION.—Section 403 (21 U.S.C. 343) is amended by adding at the end the following new paragraph:

"(q)(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

"(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

"(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

"(B) the number of servings or other units of measure per container,

"(C) the total number of calories—

"(i) derived from any source, and

"(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

"(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

"(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this Act before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

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"(2)(A) If the Secretary determines that a nutrient other than a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.

"(B) If the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

"(3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

Regulations. Agricultural commodities. Seafood.

"(4)(A) The Secretary shall provide for furnishing the nutrition information required by subparagraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by clause (B) or by issuing regulations that are mandatory as provided by clause (C).

"(B)(i) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990, the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in subparagraphs (1) and (2). Such guidelines shall take into account the actions taken by food retailers during such 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply—

"(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and

"(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

Regulations.

"(ii) Upon the expiration of 12 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subclause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.

Reports.

"(C)(i) Upon the expiration of 30 months after the date of the enactment of the Nutrition Labeling and Education Act of 1990, the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under clause

(A). Such report shall include a determination of whether there is substantial compliance with the guidelines.

"(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subclause (i) every two years.

"(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under clause (A), the Secretary shall at the time such determination is made issue proposed regulations requiring tnat any person who offers raw agricultural commodities or raw fish to consumers to provide, in a manner prescribed by regulations, the nutrition information required by subparagraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.

Regulations.
Effective date.

"(ii) Regulations issued under subclause (i) may require that the nutrition information required by subparagraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by subparagraphs (1) and (2).

"(iii) Regulations issued under subclause (i) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.

Public information.

"(E) For purposes of this subparagraph, the term 'fish' includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

"(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

"(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—

"(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

"(ii) which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,

"(iii) which is an infant formula subject to section 412,

"(iv) which is a medical food as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)), or

"(v) which is described in section 405(2).

"(B) Subparagraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such subparagraphs is impracticable because the package of such food is too small to comply with the requirements of such subparagraphs and if the label of such food does not contain any nutrition information.

"(C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

"(D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000, the requirements of subparagraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

"(E) If a food to which section 411 applies (as defined in section 411(c)) contains one or more of the nutrients required by subparagraph (1) or (2) to be in the label or labeling of the food, the label or labeling of such food shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for such food and which is specified in regulations of the Secretary.

"(F) Subparagraphs (1), (2), (3), and (4) shall not apply to food which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.".

21 USC 343 note.

(b) REGULATIONS.—

(1) The Secretary of Health and Human Services shall issue proposed regulations to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act within 12 months after the date of the enactment of this Act. Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement the requirements of such section. Such regulations shall—

Public information.

(A) require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet,

(B) include regulations which establish standards, in accordance with paragraph (1)(A), to define serving size or other unit of measure for food,

(C) permit the label or labeling of food to include nutrition information which is in addition to the information

required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

(D) permit the nutrition information on the label or labeling of a food to remain the same or permit the information to be stated as a range even though (i) there are minor variations in the nutritional value of the food which occur in the normal course of the production or processing of the food, or (ii) the food is comprised of an assortment of similar foods which have variations in nutritional value.

(2) If the Secretary of Health and Human Services does not promulgate final regulations under paragraph (1) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1) shall be considered as the final regulations upon the expiration of such 24 months. There shall be promptly published in the Federal Register notice of new status of the proposed regulations.

Federal Register, publication.

(3) If the Secretary of Health and Human Services does not promulgate final regulations under section 403(q)(4) of the Federal Food, Drug, and Cosmetic Act upon the expiration of 6 months after the date on which the Secretary makes a finding that there has been no substantial compliance with section 403(q)(4)(C) of such Act, the proposed regulations issued in accordance with such section shall be considered as the final regulations upon the expiration of such 6 months. There shall be promptly published in the Federal Register notice of new status of the proposed regulations.

Federal Register, publication.
21 USC 343 note.

(c) CONSUMER EDUCATION.—The Secretary of Health and Human Services shall carry out activities which educate consumers about—

(1) the availability of nutrition information in the label or labeling of food, and

(2) the importance of that information in maintaining healthy dietary practices.

SEC. 3. CLAIMS.

(a) LABELING REQUIRED.—Section 403 (21 U.S.C. 343) is amended by adding after the paragraph added by section 2 the following:

"(r)(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

"(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

"(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or 5(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

"(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)—

"(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

"(ii) may not state the absence of a nutrient unless—

"(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

"(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food,

Cholesterol.

"(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless—

"(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food, and

"(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

"(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,

"(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and

"(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

"(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See _____ for nutrition information.'. In the statement—

"(i) the blank shall identify the panel on which the information described in the statement may be found, and

"(ii) if the Secretary determines that the food contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the statement shall also identify such nutrient.

"(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

"(D) Subparagraph (2) does not apply to a claim described in subparagraph (1)(A) which uses the term 'diet' and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use of the term 'diet' was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to paragraph (a).

"(E) Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

"(3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made—

"(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and

"(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

Regulations.

"(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

"(ii) A regulation described in subclause (i) shall describe—

"(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health-related condition, and

"(II) the significance of each such nutrient in affecting such disease or health-related condition.

"(iii) A regulation described in subclause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

"(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary denies the petition, the petition shall not be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision.

Classified information. Regulations.

"(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

"(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

Federal Register, publication.

"(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this subsection and a summary of the scientific data which supports such reasons.

"(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

"(5)(A) This paragraph does not apply to infant formulas subject to section 412(h) and medical foods as defined in section 5(b) of the Orphan Drug Act.

"(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

"(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 401 shall not be subject to subparagraph (2)(A)(i) or (2)(B).

"(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.".

21 USC 343 note.

(b) REGULATIONS.—

(1)(A) Within 12 months of the date of the enactment of this Act, the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act. Such regulations— Regulations.

(i) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act,

(ii) shall identify claims described in section 403(r)(1)(B) of such Act which comply with section 403(r)(3) of such Act,

(iii) shall, in defining terms used to characterize the level of any nutrient in food under section 403(r)(2)(A)(i) of such Act, define—

(I) free,

(II) low,

(III) light or lite,

(IV) reduced,

(V) less, and

(VI) high,

unless the Secretary finds that the use of any such term would be misleading,

(iv) shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act,

(v) shall provide that if multiple claims subject to section 403(r)(1)(A) of such Act are made on a single panel of the food label or page of a labeling brochure, a single statement may be made to satisfy section 403(r)(2)(B) of such Act,

(vi) shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(3) of such Act: Calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease,

(vii) shall not require a person who proposes to make a claim described in section 403(r)(1)(B) of such Act which is in compliance with such regulations to secure the approval of the Secretary before making such claim,

(viii) may permit a claim described in section 403(r)(1)(A) of such Act to be made for butter,

(ix) may, in defining terms under section 403(r)(2)(A)(i), include similar terms which are commonly understood to have the same meaning, and

(x) shall establish, as required by section 403(r)(5)(D), the procedure and standard respecting the validity of claims made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances and shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(5)(D) of such Act: folic acid and neural tube defects, antioxident vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease.

(B) Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act. Regulations.

(2) If the Secretary does not promulgate final regulations under paragraph (1)(B) upon the expiration of 24 months after

the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1)(A) shall be considered as the final regulations upon the expiration of such 24 months. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations.

Federal Register, publication.

SEC. 4. STATE ENFORCEMENT.

Section 307 (21 U.S.C. 337) is amended by striking out "All such proceedings" and inserting in lieu thereof "(a) Except as provided in subsection (b), all such proceedings" and by adding at the end the following:

"(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) if the food that is the subject of the proceedings is located in the State.

"(2) No proceeding may be commenced by a State under paragraph (1)—

"(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

"(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

"(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.'

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.", and

(2) in the last sentence, by striking out "any such proceeding" and inserting in lieu thereof "any proceeding under this section".

SEC. 5. CONFORMING AMENDMENTS.

(a) SECTION 405.—Section 405 (21 U.S.C. 345) is amended by adding at the end the following: "This section does not apply to the labeling requirements of sections 403(q) and 403(r).".

(b) DRUGS.—Section 201(g)(1) (21 U.S.C. 321(g)(1)) is amended by adding at the end the following: "A food for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug under clause (B) solely because the label or labeling contains such a claim.".

SEC. 6. NATIONAL UNIFORM NUTRITION LABELING.

(a) PREEMPTION.—Chapter IV is amended by adding after section 403 the following new section:

21 USC 343-1.

"SEC. 403A. (a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

"(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g),

"(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), or 403(i)(2) that is not identical to the requirement of such section,

"(3) any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) that is not identical to the requirement of such section,

"(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q), except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A), or

"(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r), except a requirement respecting a claim made in the label or labeling of food which is exempt under clause (B) of such section.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

"(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation; any State or local requirement that—

"(1) would not cause any food to be in violation of any applicable requirement under Federal law,

"(2) would not unduly burden interstate commerce, and

"(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a).".

(b) STUDY AND REGULATIONS.—

21 USC 343-1 note. Government contracts.

(1) For the purpose of implementing section 403A(a)(3), the Secretary of Health and Human Services shall enter into a contract with a public or nonprofit private entity to conduct a study of—

(A) State and local laws which require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act, and

(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

(2) The contract under paragraph (1) shall provide that the study required by such paragraph shall be completed within 6 months of the date of the enactment of this Act.

(3)(A) Within 9 months of the date of the enactment of this Act, the Secretary shall publish a proposed list of sections which are adequately being implemented by regulations as determined under paragraph (1)(B) and sections which are not adequately being implemented by regulations as so determined. After publication of the lists, the Secretary shall provide 60 days for comments on such lists.

(B) Within 24 months of the date of the enactment of this Act, the Secretary shall publish a final list of sections which are adequately being implemented by regulations and a list of sections which are not adequately being implemented by regulations. With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision

of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to the requirement of such section.

(C) Within 24 months of the date of the enactment of this Act, the Secretary shall publish proposed revisions to the regulations found to be inadequate under subparagraph (B) and within 30 months of such date shall issue final revisions. Upon the effective date of such final revisions, no State or political subdivision may establish or continue in effect any requirement which is not identical to the requirement of the section which had its regulations revised in accordance with this subparagraph.

(D)(i) If the Secretary does not issue a final list in accordance with subparagraph (B), the proposed list issued under subparagraph (A) shall be considered the final list and States and political subdivisions shall be preempted with respect to sections found to be adequate in such proposed list in accordance with subparagraph (B).

(ii) If the Secretary does not issue final revisions of regulations in accordance with subparagraph (C), the proposed revisions issued under such subparagraph shall be considered the final revisions and States and political subdivisions shall be preempted with respect to sections the regulations of which are revised by the proposed revisions.

(E) Subsection (b) of section 403A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the prohibition prescribed by subparagraphs (B) and (C).

21 USC 343-1 note.

(c) CONSTRUCTION.—

(1) The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act.

(2) The amendment made by subsection (a) and the provisions of subsection (b) shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.

(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code.

SEC. 7. INGREDIENTS.

Section 403(i) (21 U.S.C. 343(i)) is amended—

(1) by striking out "If it is not subject to paragraph (g) of this section unless" and inserting in lieu thereof "Unless",

(2) by inserting before "; except" the following: "and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food", and

(3) by striking out "colorings" and inserting in lieu thereof "colors not required to be certified under section 706(c)".

SEC. 8. STANDARD OF IDENTITY REGULATION.

Section 701(e) (21 U.S.C. 371(e)) is amended by striking out "Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502 (d) or (h) of this Act" and inserting in lieu thereof the following: "Any action for the issuance, amendment, or repeal of any regulation under section 403(j), 404(a), 406, 501(b), or 502 (d) or (h) of this Act, and any action for the amendment or repeal of any definition and standard of identity under section 401 of this Act for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations).

SEC. 9. CONSTRUCTION. 21 USC 343 note.

The amendments made by this Act shall not be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

SEC. 10. EFFECTIVE DATE. 21 USC 343 note.

(a) IN GENERAL.—

(1) Except as provided in paragraph (2)—

(A) the amendments made by section 2 shall take effect 6 months after—

(i) the date of the promulgation of all final regulations required to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act, or

(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations,

except that section 403(q)(4) of such Act shall take effect as prescribed by such section,

(B) the amendments made by section 3 shall take effect 6 months after—

(i) the date of the promulgation of final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, or

(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations, except that any person marketing a food the brand name of which contains a term defined by the Secretary under section 403(r)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act shall be given an additional 6 months to comply with section 3,

(C) the amendments made by section 4 shall take effect 24 months after the date of the enactment of this Act, and

(D) the amendments made by section 5 shall take effect on the date the amendments made by section 3 take effect.

(2) Section 403(q) of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 2 and section 403(r) of the Federal Food, Drug, and Cosmetic Act (as added by section 3) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 3.

(3)(A) If the Secretary finds that a person who is subject to section 403(q)(4) of such Act is unable to comply with the requirements of such section upon the effective date of final regulations to implement section 403(q) of such Act or of proposed regulations to be considered as such final regulations because the Secretary has not made available to such person the information required by such section, the Secretary shall delay the application of such section to such person for such time as the Secretary may require to provide such information.

(B) If the Secretary finds that compliance with section 403(q) or 403(r)(2) of such Act would cause an undue economic hardship, the Secretary may delay the application of such sections for no more than one year.

21 USC 343-1 note.

(b) SECTION 6.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by section 6 shall take effect—

(A) with respect to a requirement of a State or political subdivision described in paragraph (1) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date of the enactment of this Act,

(B) with respect to a requirement of a State or political subdivision described in paragraph (2) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, one year after the date of the enactment of this Act,

(C) with respect to a requirement of a State or political subdivision described in paragraph (3) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, as prescribed by section 6(b) of the Nutrition Labeling and Education Act of 1990,

(D) with respect to a requirement of a State or political subdivision described in paragraph (4) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date regulations to implement section 403(q) of such Act take effect, and

(E) with respect to a requirement of a State or political subdivision described in paragraph (5) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date regulations to implement section 403(r) of such Act take effect.

(2) EXCEPTION.—If a State or political subdivision submits a petition under section 403A(b) of the Federal Food, Drug, and Cosmetic Act for a requirement described in section 403A(a) of such Act within 18 months of the date of the enactment of this Act, paragraphs (3) through (5) of such section 403A(a) shall not apply with respect to such State or political subdivision requirement until—

(1) 24 months after the date of the enactment of this Act, or
(2) action on the petition,
whichever occurs later.

(c) SECTION 7.—The amendments made by section 7 shall take effect one year after the date of the enactment of this Act. 21 USC 343 note.

Approved November 8, 1990.

LEGISLATIVE HISTORY—H.R. 3562:

HOUSE REPORTS: No. 101-538 (Comm. on Energy and Commerce).
CONGRESSIONAL RECORD, Vol. 136 (1990):
July 30, considered and passed House.
Oct. 24, considered and passed Senate, amended.
Oct. 26, House concurred in Senate amendments.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 26 (1990):
Nov. 8, Presidential statement.

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